



**AMO ENDOSOL**

(AMO)

**Description:**

AMO Endosol solution for irrigation is a sterile, lint free, physiological balanced salt solution. Each mL contains **sodium chloride** BP 6.4 mg, **potassium chloride** BP 0.75 mg, **calcium chloride** BP 0.48 mg, **magnesium chloride** BP 0.3 mg, **sodium acetate** BP 3.9 mg, **sodium citrate** BP 1.7 mg, sodium hydroxide BP and/or hydrochloric acid BP (to adjust pH) in Water for Injections BP.

**Pharmacology:**

AMO Endosol solution for irrigation is isotonic to the tissues of the eyes. It is intended for use as a physiological solution for irrigation. There are no therapeutically or pharmacologically active ingredients contained in AMO Endosol solution for irrigation.

**Indications:**

For irrigation during various surgical procedures of the eyes.

**Contra-indications:**

There are no known contraindications for the use of AMO Endosol solution as an irrigation solution during surgical procedures of the eyes.

**Precautions:**

General: AMO Endosol solution for irrigation is not to be used for injection or intravenous infusion. Each container of AMO Endosol solution for irrigation should be used for one patient only. AMO Endosol solution for irrigation does not contain a preservative and should not be reused after opening.

Precautions in special populations: Studies suggest that intraocular irrigating solutions which are iso-osmotic with normal aqueous fluids should be used with caution in diabetic patients undergoing vitrectomy since intraoperative lens changes have been observed.

There have been reports of corneal clouding and oedema following ocular surgery in which a balanced salt solution was used as an irrigating solution. As in all surgical procedures, appropriate measures should be taken to minimise trauma to the cornea and other ocular tissues.

Check the following before use: Prior to using AMO Endosol solution, ensure that the solution is clear and free of particulate matter. Use only if the seal is undamaged and a vacuum is present in the bottles.

**Interactions with other drugs:**

AMO Endosol solution for irrigation should not be mixed with any other

solution or therapeutic agent, as ocular tissue damage may result.

**Use in pregnancy and lactation:**

AMO Endosol solution for irrigation contains no therapeutically or pharmacologically active ingredient and is not intended to be absorbed. Therefore it poses no special threat to pregnancy or lactation.

**Adverse Reactions:**

When the corneal epithelium is abnormal, excessive intraocular irrigation or any other trauma may result in bullous keratopathy. Post operative inflammatory reactions as well as incidents of corneal oedema and corneal decompensation have been reported. Their relationship to the balanced salt solution used has not been established.

**Dosage and Administration:**

The dosage of AMO Endosol solution for irrigation is dictated by the standard format for each surgical procedure. AMO Endosol solution should be opened only under aseptic conditions.

Viaflex bags: Tear overpouch down the side at the slit and remove solution bag. Some opacity of the plastic due to moisture absorption during the sterilisation process may be observed. This is normal and does not affect the solution quality or safety. The opacity will diminish gradually. Check for minute leaks by squeezing bag firmly. If leaks are found, discard solution as sterility may be impaired. Use aseptic technique to open bag. Suspend the bag using the hanger hole and remove the plastic protector from the outlet port at the bottom of the container (blue tip). Attach irrigation set (Refer to the complete directions accompanying the set). Discard any unused portion.

Glass bottles: Use an administration set with an air inlet in the plastic spike since the bottle does not contain a separate airway tube. Follow directions for the particular administration set to be used. Remove aluminium cap from the glass bottles and insert spike aseptically through the centre target area of the rubber stopper. Allow fluid to move and air to flow before commencing irrigation.

**Overdosage:**

AMO Endosol solution for irrigation has no therapeutic action and overdosage does not pose a threat. However, as for any surgical procedure, the duration should be kept to a minimum.

**Storage:**

Viaflex bags: Store below 30°C. Do not freeze.

Glass bottles: Store below 25°C. Do not freeze.

**Pack:**

AMO Endosol solution for irrigation is supplied sterile in two container

## Alcon Citizen Petition - Balanced Salt Solution

types:

1. Viaflex bags: 250 mL and 500 mL (plasticised polyvinyl chloride bags sealed inside pre-shaped, transparent, high density polyethylene overpouches).
2. Glass bottles: 500 mL (sealed with a rubber stopper and secured by a 3 piece aluminium Steriseal cap).

Balanced Salt Solution for irrigation bag; AUST R 61825  
Balanced Salt Solution for irrigation bottle; AUST R 61824

No Restriction—Any State and A.C.T.

TGA approval date: 14 November 1997

Should you  
have any  
further  
questions please  
**click here** to  
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